

**PA DEP NERO****Region II****Application Review Memo**

<b>Date</b>	April 22, 2016
<b>Permit Reviewer</b>	David F. Matcho
<b>Title V Chief</b>	Norman Frederick
<b>Air Quality Program Manager</b>	Mark Wejkszner
<b>Application No. (File No.)</b>	TV- 39-00055
<b>Owner of Sources</b>	B. Braun Medical, Inc.
<b>Source Description</b>	Medical Device Mfr.
<b>Control Equipment</b>	catalytic oxidizer, wet scrubber
<b>Location of Sources</b>	Hanover Township, Lehigh County

**General Information**

On July 4, 2014, the Department received a renewal Title V operating permit renewal application from B. Braun Medical, Inc., for its medical device manufacturer located in Hanover Township, Lehigh County. The application was complete and signed by a responsible official. The permittee has submitted the proper application fee, copies of county and municipal notification letters and a compliance history. The permittee is currently operating under operating permit #39-00055 issued on 01/13/2010.

**Facility/Source Description**

The facility is a medical device manufacturer. Sources at the facility include eight (8) sterilizers using ethylene oxide, three (3) emergency generators, two (2) fire pumps, one (1) F-Line, one (1) Introcan Line.

**Control Devices**

The facility uses a catalytic oxidizer and a wet scrubber. The wet scrubber is used for the sterilizers. The catalytic oxidizer is used for the aeration room.

**Regulatory Analysis**

Emissions from the facility emissions report of year 2014 submitted to the Department include Carbon Monoxide (CO): 3.30 tpy. Nitrogen Oxides (NOx): 4.10 tpy, Particulate Matter (PM, PM10, PM2.5): 0.2 tpy, Sulfur Oxides (SO2): 0.0 tpy, Volatile Organic Compounds (VOC): 3.70 tpy.

The facility is an area source for Hazardous Air Pollutants.

Source ID 111, emergency generator 2, is not subject to New Source Performance Standards, 40 CFR 60, Subpart JJJJ, Spark Ignition Internal Combustion Engines based on the being installed in 1989.

Sources of Group-1 are subject to 40 CFR 63, Subpart O, Ethylene Oxide Emissions Standards for Sterilization Facilities.

a) Source ID 003 and 004 in Group 2 are subject to 40 CFR 60 Subpart IIII - Standards of Performance for Stationary Compression Ignition Internal Combustion Engines.

b) Source ID 111, 112, 113 and 115 in Group 2 are subject to 40 CFR Part 63 Subpart ZZZZ, for Stationary Reciprocating Internal Combustion Engines.

The following new sources have been added to the facility:

Source ID 115 – Fire Pump 3

Source ID 116 – F-Line

Source ID 117 – Introcan

(Reference: Request for Determination(s) (RFD)

#39-0700 approved 05/24/2011 installation of a new pharmacy assembly line; F-Line.

#39-0777 approved 08/19/2013 operation of equipment used to dispose of medical devices; Introcan Operation.

#39-0802 approved 03/25/2014 operation of 115-Fire Pump.

The facility has removed the use of #6 fuel oil in all sources.

(Reference: #39-0801 approved 03/25/2014 ceased firing #6 fuel oil in boiler #032)

The following sources have been removed from the facility:

Source ID 031 – Boiler, Kewanee (19.5 MMBtu/hr)

### **Site Level Requirements**

The facility is subject to emission restrictions for certain fugitive emissions (25 Pa. Code Section 123.1), fugitive particulate matter (25 Pa. Code Section 123.2), malodors (25 Pa. Code Section 123.31) and visible air contaminants (25 Pa. Code Section 123.41) and Exceptions (25 Pa. Code Section 123.42).

### **Testing Requirements**

All sampling, testing and analysis performed in compliance with the requirements of any section of this permit shall be done in accordance with General Title V Requirements #021.

Upon the request of the Department, the person responsible for a source shall provide adequate sampling ports, safe sampling platforms and adequate utilities for the performance by the Department of tests on such source. The Department will set forth, in the request, the time period in which the facilities shall be provided as well as the specifications for such facilities.

Sampling and testing done by persons other than the Department may be accepted by the Department provided that:

- (1) The Department has been given reasonable notice of the sampling and testing and has been given reasonable opportunity to observe and participate in the sampling and testing.
- (2) The sampling and testing is conducted under the direct supervision of persons qualified, by training and experience, to conduct such sampling and testing.
- (3) Procedures for the sampling and testing are in accord with the provisions of this chapter.
- (4) The reports of the sampling and testing are accurate and comprehensive.

### **Monitoring Requirements**

The permittee shall perform weekly monitoring of the plant property for visible and fugitive visible emissions in accordance with 25 Pa. Code Section 123.43. The permittee shall conduct a monthly inspection during daylight hours when the plant is in production to inspect for visible, fugitive, and malodor emissions. If visible, fugitive or malodor emissions are detected, corrective actions shall be taken immediately to abate the emission.

### **Recordkeeping Requirements**

All monthly inspection results for visible, fugitive, or malodor emissions, shall be recorded in a logbook. The logbook shall be maintained on-site and be made available to the Department upon request. At a minimum, the permittee shall record the date, time, results of the inspection, and individual conducting the inspection.

All records, reports, and analysis results generated in compliance with the requirements of any section of this permit shall be maintained in accordance with General Title V Requirement #022, Section B, and shall be made available to the Department upon written or verbal request at a reasonable time.

### **Reporting Requirement**

- 1) The company, within one hour of occurrence, shall notify the Department, at 610-861-2070, of any malfunction of the source(s) or associated air cleaning device(s) which results in, or may possibly be resulting in, the emission of air contaminants in excess of the limitations specified in, or established pursuant to, any applicable rule or regulation contained in Article III of the Rules and Regulations of the Department of Environmental Protection. A written report shall be submitted to the Department within two working days following the incident describing the malfunctions and corrective actions taken.
- 2) Any changes in the location of the aforementioned source, or any changes in the process or control equipment would be consider a modification and would require the submittal of an amended application for plan approval in accordance with the provisions of 25 PA Code 127.11 and 127.12.
- 3) Any notification as a result of any condition herein should be directed to:  
Air Quality Program Manager  
Department of Environmental Protection  
2 Public Square  
Wilkes-Barre, PA 18711-0790

On a quarterly basis, the permittee shall compile a report of all logged instances of exceedance of the fugitive, visible and malodor emission limitations, as required by Site  
B. Braun Medical, Inc. 3 April 22, 2016  
TV-39-00055

Level Conditions #001, #003 and #004, that occurred during the previous three (3) months. These reports shall be submitted to the Department within thirty (30) days of the close of the calendar quarter. If no deviations were detected this report shall be retained on site and made available the Department upon request.

The reporting period for the certificate of compliance required by condition #024 of Section B, shall be for the previous calendar year, and it shall be submitted within 60 days after the specified period but no later than March 1st.

### **Work Practice Standards**

The permittee shall take reasonable actions to prevent particulate matter from becoming airborne. These actions shall include, but not be limited to, the following:

- (1) Use, where possible, of water or chemicals for control of dust in the demolition of buildings or structures, construction operations, the grading of roads, or the clearing of land.
- (2) Application of asphalt, oil, water or suitable chemicals on dirt roads, material stockpiles and other surfaces which may give rise to airborne dusts.
- (3) Paving and maintenance of roadways.
- (4) Prompt removal of earth or other material from paved streets onto which earth or other material has been transported by trucking or earth moving equipment, erosion by water, or other means.

The permittee shall not conduct open burning in accordance with 25 Pa. Code Section 129.14.

### **Additional Requirements**

The permittee may not permit the presence in the outdoor atmosphere of any form of contaminant, including, but not limited to, the discharging from stacks, chimneys, openings, buildings, structures, open fires, vehicles, processes or any other source of any smoke, soot, fly ash, dust, cinders, dirt, noxious or obnoxious acids, fumes, oxides, gases, vapors, odors, toxic, hazardous or radioactive substances, waste or other matter in a place, manner or concentration inimical or which may be inimical to public health, safety or welfare or which is or may be injurious to human, plant or animal life or to property or which unreasonably interferes with the comfortable enjoyment of life or property.

### **Source Level Requirements**

#### **Source ID 003**

The permittee is subject to 40 CFR Part 60 Standards of Performance for New Stationary Sources §40 CFR, 60.4205 Subpart IIII - Standards of Performance for Stationary Compression Ignition Internal Combustion Engines.

What emission standards must I meet for emergency engines if I am an owner or operator of a stationary CI internal combustion engine?

(b) Owners and operators of 2007 model year and later emergency stationary CI ICE with a displacement of less than 30 liters per cylinder that are not fire pump engines

must comply with the emission standards for new non-road CI engines in §60.4202, for all pollutants, for the same model year and maximum engine power for their 2007 model year and later emergency stationary CI ICE.

The permittee is subject to 40 CFR Part 60 Standards of Performance for New Stationary Sources §40 CFR 60.4211, Subpart IIII - Standards of Performance for Stationary Compression Ignition Internal Combustion Engines.

What are my compliance requirements if I am an owner or operator of a stationary CI internal combustion engine?

(a) If you are an owner or operator and must comply with the emission standards specified in this subpart, you must operate and maintain the stationary CI internal combustion engine and control device according to the manufacturer's written instructions or procedures developed by the owner or operator that are approved by the engine manufacturer. In addition, owners and operators may only change those settings that are permitted by the manufacturer. You must also meet the requirements of 40 CFR parts 89, 94 and/or 1068, as they apply to you.

#### **Source ID 004**

The permittee is subject to 40 CFR Part 60 Standards of Performance for New Stationary Sources §40 CFR 60.4205, Subpart IIII - Standards of Performance for Stationary Compression Ignition Internal Combustion Engines, What emission standards must I meet for emergency engines if I am an owner or operator of a stationary CI internal combustion engine?

(c) Owners and operators of fire pump engines with a displacement of less than 30 liters per cylinder must comply with the emission standards in table 4 to this subpart, for all pollutants.

The permittee is subject to 40 CFR Part 60 Standards of Performance for New Stationary Sources §40 CFR 60.4211, Subpart IIII - Standards of Performance for Stationary Compression Ignition Internal Combustion Engines, What are my compliance requirements if I am an owner or operator of a stationary CI internal combustion engine?

(a) If you are an owner or operator and must comply with the emission standards specified in this subpart, you must operate and maintain the stationary CI internal combustion engine and control device according to the manufacturer's written instructions or procedures developed by the owner or operator that are approved by the engine manufacturer. In addition, owners and operators may only change those settings that are permitted by the manufacturer. You must also meet the requirements of 40 CFR parts 89, 94 and/or 1068, as they apply to you.

#### **Source ID 113**

The permittee is subject to 40 CFR 63.6604, Subpart ZZZZ - National Emissions Standards for Hazardous Air Pollutants for Stationary Reciprocating Internal Combustion Engines, What fuel requirements must I meet if I own or operate an existing stationary CI RICE?

Beginning January 1, 2015, if you own or operate an existing emergency CI stationary RICE with a site rating of more than 100 brake HP and a displacement of less than 30 liters per cylinder that uses diesel fuel and operates or is contractually obligated to be available for more than 15 hours per calendar year for the purposes specified in §63.6640(f)(2)(ii) and (iii) or that operates for the purpose specified in §63.6640(f)(4)(ii), you must use diesel fuel that meets the requirements in 40 CFR 80.510(b) for non-road diesel fuel, except that any existing diesel fuel purchased (or otherwise obtained) prior to January 1, 2015, may be used until depleted.

#### **Group – 1 (101, 102, 103, 104, 105, 106, 107, 108, 110)**

The sources of Group-1 are subject to 40 CFR 63, Subpart O, Ethylene Oxide Emissions Standards for Sterilization Facilities. (63.362, 63.363, 63.364, 63.365, 63.366, 63.367)

1. Minimum oxidation temperature for the Donaldson catalytic oxidizer shall be 253 deg F (low level EtO concentration) and 258 deg F (high level EtO concentration).
2. Chemrox Deoxs scrubber liquid level maximum shall be 126 inches.

#### **Section H – Miscellaneous**

- a) This is a renewal of operating permit TV-39-00055.
  - b) This is a Title V Operating Permit facility.
  - c) Source ID 031 and 032 (boilers and stacks) have been removed from the facility.
  - d) The permittee is deactivating Source 114 (emergency generator, Kohler 30 kW; natural gas) pursuant to 25 Pa. Code Chapter 127.11a.
  - e) The facility no longer fires #6 fuel oil in any of its sources.
- The Title V renewal application was received on 07/04/2014 and updated on 12/12/2014.
- Request for Determination(s) (RFD):
- #39-0700 approved 05/24/2011 installation of a new pharmacy assembly line; F-Line.
- #39-0777 approved 08/19/2013 operation of equipment used to dispose of medical devices; Introcan Operation.
- #39-0801 approved 03/25/2014 ceased firing #6 fuel oil in boiler #032.
- #39-0802 approved 03/25/2014 operation of 115-Fire Pump.
- Plan Approvals:
- 39-332-001 issued 03/23/2010 for reactivation of Source 109 (was not reactivated)
- 39-332-002 issued 02/29/2012 for reactivation of Source 109 (was not reactivated)

#### **Recommendation**

Based on the renewal Title V operating permit application and information submitted by the permittee, I recommend that a renewal Title V Operating Permit be issued to B. Braun Medical, Inc., located in Hanover Township, Lehigh County. The operating permits contains all applicable Federal and State requirements regarding compliance including emission restrictions, testing, monitoring, recordkeeping, reporting, work practice standards and any additional requirements.